

Attorney Docket No.: DRE-0067  
Inventors: Laurencin et al.  
Serial No.: 10/052,121  
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#### REMARKS

Claims 1-3, 5 and 6 are pending in the instant application. Claims 1-3, 5 and 6 have been rejected. Claim 1 has been amended. Support for amendments to claim 1 are provided in the specification at page 8, line 1 and page 8, line 9, line 25 through page 8, line 15, page 9, lines 4-13, page 10, lines 18-22, and page 13, lines 9-14. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Rejection of Claims 1-3, 5 and 6 under 35 U.S.C. 112, first paragraph - Written Description

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner suggests that the specification discloses microcarrier diameter as 500 to 860  $\mu\text{m}$  and not the pore size, which is disclosed as 113 to 356  $\mu\text{m}$ .

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to state that the microcarriers range from 500 to 860  $\mu\text{m}$  in diameter and are bonded together into a scaffold with a fully interconnected pore network with a pore size range of 113 to 356  $\mu\text{m}$ . As acknowledged by the Examiner, support for this amendment is provided in teachings at page 8, lines 1 and 9. Thus no new matter is added by this amendment.

Withdrawal of this rejection is respectfully requested in light of this amendment.

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**II. Rejection of Claims 1-3, 5 and 6 under 35 U.S.C. 112, second paragraph**

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that claim 1 is confusing for reciting "interconnected" in lines 5 and 6.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete "interconnected" in line 5.

Withdrawal of this rejection is therefore respectfully requested.

**III. Rejection of Claims under 35 U.S.C. § 35 U.S.C. 103(a)**

The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Starling et al. (U.S. Patent 6,210,715) in view of Crofts et al. has been maintained.

Arguments presented by Applicants in the last response were deemed unpersuasive. In particular, arguments presented by Applicants that Crofts et al. does not teach the same microcarrier size range were found unconvincing because the claim did not specify a microcarrier size range, but rather a pore size range. Further, the Examiner suggests that Starling et al. disclose a microsphere size of 500-1000  $\mu\text{m}$  and the Examiner suggests that there is seen nothing to lead one to believe that microspheres cannot be made from PLGA having a size as taught by Starling et al. In addition, with respect to the pores of the instant claimed scaffold being interconnected, the Examiner

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suggests that the aggregate of Starling et al. has an interconnect porosity (col. 6, line 32) and that when the particle size of the microsphere of Starling et al. are within the range of 500-1000  $\mu\text{m}$ , the pores will be fully interconnected.

The rejection of claims 2, 3, 5 and 6 under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1, and further in view of Spaulding (U.S. Patent 6,001,643) and Granet et al. (reference AJ on 1449) has also been maintained. In particular, the Examiner suggests that for the above-stated reasons, Starling and Crotts et al. are not believed deficient.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the claims have been amended to state that the scaffold comprises microcarriers ranging from 500 to 860  $\mu\text{m}$  in diameter bonded together into a three dimensional scaffold with a fully interconnected pore network with a pore size range of 113 to 356  $\mu\text{m}$ . Thus, the claims as amended are distinguishable from Crotts et al., which only teaches PLGA microcarriers with sizes up to 350  $\mu\text{m}$ .

Further, Applicants respectfully disagree with the Examiner's suggestion that "there is seen nothing to lead one to believe that microspheres" and scaffolds of microspheres with the instant claimed characteristics "cannot be made from PLGA having a size as taught by Starling et al."

As taught at page 98 of Crotts et al. larger microspheres prepared from formulation D with sizes ranging up to 350  $\mu\text{m}$  had highly porous surfaces characterized by Crotts et al. as a 'sponge-like' porous structure. In contrast, the network of

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pores of the scaffold of the instant invention is stated in the claims to be fully interconnected, thus indicating that the microspheres themselves are not porous nor 'sponge-like'. Thus, contrary to the Examiner's suggestion, teachings of Crotts lead the skilled artisan away from the expectation that PLGA microcarriers in the size range taught by Starling et al. could be bonded to produce a scaffold with a fully interconnected pore network as claimed.

Finally, with respect to the Examiner's suggestion that the aggregate of Starling et al. has an interconnect porosity (col. 6, line 32) and that when the particle size of the microsphere of Starling et al. are within the range of 500-1000  $\mu\text{m}$ , the pores will be fully interconnected, it is respectfully pointed out that at col. 9, lines 2-5, of Starling et al., it is taught that compacts of microspheres in the size range of 500-1000  $\mu\text{m}$  produce an interstitial open porosity of about 60% with a pore size range of about 350 micrometers to about 500 micrometers. In contrast, claims of the instant application have been amended in accordance with teachings at page 8, line 9, to state that the interconnected pores range in size from 113 to 356  $\mu\text{m}$ .

Accordingly, the combined teachings of Crotts et al. and Starling et al. do not teach or suggest a scaffold with all the limitations of the instant claimed scaffold and thus this combination of references cannot render obvious the invention as claimed.

Further, the secondary references cited by the Examiner in the rejection of dependent claims 2, 3, 5 and 6, namely Spaulding (U.S. Patent 6,001,643) and Granet et al., fail to remedy the

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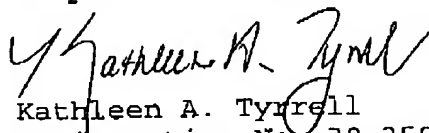
deficiencies in teachings of Starling et al. and Crofts et al.  
with respect to the instant claimed invention.

Withdrawal of these rejections under 35 U.S.C. 103 is  
therefore respectfully requested.

#### IV. Conclusion

Applicants believe that the foregoing comprises a full and  
complete response to the Office Action of record. Accordingly,  
favorable reconsideration and subsequent allowance of the pending  
claims is earnestly solicited.

Respectfully submitted,

  
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Date: January 17, 2006

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